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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,477

01/09/2007

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Q94121

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,477	<b>Applicant(s)</b> SUDOH ET AL.	
	<b>Examiner</b> Sudhakar Katakam	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-16, 23-28, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-16, 23-28, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the application***

1. Receipt of Applicant's remarks and arguments filed on 19<sup>th</sup> Feb 2008 is acknowledged. In view of applicants' filed terminal disclaimer, the previous obviousness-type double patenting rejection has been withdrawn.
2. With regard to the 103(a) rejection, the applicants' arguments are not found persuasive. However, upon further consideration, in view of applicants' amendments to the claims, a new ground(s) of rejection is made in view of different interpretation of the previously applied reference, newly found prior art references, and provide an explanation of the rejection.
3. Claims 6, 17, 20-22, 32 have been cancelled.
4. Claims 1, 7, 11 and 14 have been amended.
5. Claims 18-19 and 29-31 have been withdrawn.
6. Claims 1-5, 7-16, 20-28 and 33-34 are discussed on the merits in this action.

### **Claim Rejections - 35 USC § 103**

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-5, 7-16, 20-28, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hasegawa et al** (Bull.Chem.Soc.Jpn. 2000, 73, 423-428) or **JP 8291106** in view of **Ohuchida et al** (US 6,201,021) and **Black** (US 6,043,223).

**Hasegawa et al** disclose an optically active (R)-2-propyloctanoic acid, valuable therapeutic agent for neurodegenerative diseases such as Alzheimer's disease (see equation 1 in page 423 and introduction).

**JP 8291106** also discloses a salt of optically active (2R)-2-propyloctanoic acid for use in treating neurodegenerative disorders (see Abstract, translation is pending, and attached Derwent abstract).

The difference between the instant claims and the references is that the references teach the compound or its salt and silent on the source of metal ion, pH and the concentration of the components in the medicament. However **Black** cures this deficiency.

**Black** teaches use of phosphate buffer saline solution as a carrier for the bradykinin, comprises 10-40 micrograms/mL of bradykinin and 0.09% phosphate buffered saline solution [col. 5, lines 41-45]. **Black** also teaches infusion

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preparation of bradykinin that is dissolved in aqueous solution containing sodium hydroxide and phosphate buffered saline solution [col. 5, lines 47-62].

Preparation of infusions for drugs, such as (2R)-2-propyloctanoic acid, are known in the art. Also the process of adjusting pH using buffers is also very well known procedure in the art.

**Ohuchida et al** teach suitable basic metal ions for the preparation of salts of pentanoic acid derivatives [col.17, lines 1-24].

It would have been obvious to a person of ordinary skill in the art at the time of the invention to use the teachings of the above cited references and known methods, to make the composition of (2R)-2-propyloctanoic acid with basic metal ions, from the art, and to make the instant applicants medicament with a reasonable expectation of success. One would have been motivated to arrive instant claims because **Hasegawa et al** teach “preparation of (2R)-2-propyloctanoic acid” and this compound is a therapeutic agent of neurodegenerative diseases such as Alzheimer’s disease. Therefore, one would combine the teachings of the references in order to provide for a medicament mixing the (2R)-2-propyloctanoic acid with a basic metal ion in order to provide for better stability of the composition in storage. For the foregoing reasons the instant claims are made obvious.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/  
Examiner, Art Unit 1621

/Peter G O'Sullivan/

Primary Examiner, Art Unit 1621